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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,040	06/23/2004	Hans-Michael Eggenweiler	MERCK-2893	5203

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EXAMINER

MOORE, SUSANNA

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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02/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,040	Applicant(s) EGGENWEILER ET AL.	
	Examiner SUSANNA MOORE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 13, 14, 22, 23 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 13, 14 and 23 is/are allowed.
- 6) ☒ Claim(s) 22 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, see Remarks, filed 12/21/2007, with respect to Office Action mailed 10/17/2007 have been fully considered. Some of the rejections have been withdrawn and others have been maintained, while others are new. Thus, the office action is a NonFinal Office Action. In summary, claims 9, 13, 14, 22, 23 and 30 are pending from the original submission.

Claim Objections

The objection of claim 25 for the replacement of the word "an" with "a" in front of "viral" on page 7 of the claims is withdrawn based on the cancellation of said claim.

The objection of claim 30 for the word "benzoxaolamine" in section b is withdrawn based on the amendment.

The objection of claim 14 for a statement of intended use is withdrawn based on the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 13, 14, and 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 9, 13, 14, and 22-30 for the word “derivatives” is withdrawn based on the amendments.

The rejection of claims 24, 25 and 30, for the phrase "including" is withdrawn based on the amendments.

The rejection of claims 24-29 for the phrase “wherein the disease or disorder is...” is withdrawn based on the cancellation of said claims.

The therapeutic agents in claims 22 and 30 are relative terms, which renders the claim indefinite. The terms “one further medicament active ingredient,” “PDE IV or VII inhibitors,” “tryptase inhibitors” and “MAP kinase inhibitors” among others are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprized of the scope of the invention. The nature of the instant invention where the method of use claims consist of the compounds according to claim 9 and an additional active ingredient, i.e. agents for promoting growth hormone secretion, which is a therapeutic agent.

Applicant traverses the above rejection by stating, “The terms such as "PDE IV or VII inhibitors," tryptase inhibitors," and "MAP kinase inhibitors" are not "relative terms" as alleged

in the Office action. Relative terms are terms such as "higher" or "stronger." The terms objected to here are not relative in any sense. The terms define classes of therapeutic agents which are well known to one of ordinary skill in the art. One of ordinary skill in the art in the pharmaceutical arts is well aware of the meaning and metes and bounds of these terms. Further, one of ordinary skill in the art could carry out routine experimentation using known assays to determine whether a specific therapeutic agent is within such a class of agents. Additionally, the instant application provides a great deal of guidance to the reader on the nature of the additional therapeutic agent. Claim 30 itself evidences the wealth of guidance provided to applicants for selecting an appropriate additional therapeutic agent."

This is not found persuasive. The rejection of claim 30 was on the grounds that it is indefinite, in that it is not known which "agents" are capable of being responsive to the inhibition, for example of PDE IV or PDE VII. The scope of "agents" associated with inhibitory activity could alter over time. Applicant is not entitled to preempt the efforts of others. Claim 30 does not set forth the metes and bounds of said claim.

The rejection of claims 9, 13, 14 and 24-30 under 35 U.S.C. 1 12, first paragraph, for prodrugs is withdrawn based on the amendments.

Allowable Subject Matter

Claims 9, 13, 14 and 23 contain allowable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624